UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456 Civil Action No. 01-12257-PBS
	)	Hon. Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	)	

THE SCHERING-PLOUGH GROUP'S INDIVIDUAL
SUR-REPLY IN OPPOSITION TO CLASS CERTIFICATION

[REDACTED VERSION]

The Plaintiffs' reply to Schering distorts key features of the generic drug market and ignores others; it does not address the link between the economic forces affecting reimbursement of self-administered drugs and those affecting reimbursement of physician-administered drugs. Here we redress those deficiencies.

I. Self-Administered Drugs

As previously shown and not seriously contested, knowledge, leverage, and competition affect reimbursement of pharmacies for branded and generic drugs, and they belie the Plaintiffs' contention that changes in AWP have a predictable and consistent impact on pharmacy reimbursement rates. These forces affect pricing in ways that cannot be simplistically "smoothed" away by averaging. AWP is a benchmark – essentially a unit of measurement – for pricing drugs dispensed by pharmacies. As such, the effects of a change in AWP could not be uniform and predictable unless the economic forces operating in the market are themselves uniform and predictable, which they have been shown not to be.

The evidence has shown that the pricing of generic drugs is even more context-dependent and less predictable than the pricing of branded drugs. Competition among generic manufacturers operating within a spot market causes significant pressures to lower prices through increasing discounts and rebates. Here, even more than with branded drugs sold through pharmacies, tracing the impact of changes in AWP through these many and varied layers of influences defies simplistic averaging.[1]

[1] Plaintiffs' reliance on the Complaint filed by Dey, Inc. and Dey's testimony before Congress about the role of AWP in the pricing of generic drugs is misplaced. No market benchmark can be changed with respect to a single participant in a complex, multiple-source market without disastrous consequences, which is the point of Dey's testimony and pleading. Dey's testimony was that a single generic manufacturer cannot unilaterally lower its AWP in a competitive, multi-source context, because Medicaid providers will not buy the drug with the lower AWP. Congressman Mike Rogers (R-MI) noted afterwards: "when I look at the fact that there is real (sic) no guidance in this AWP… if we have found an enemy in this whole thing, it is us, uh, the United States Congress." Tr. of December 7, 2004 Congressional Hr'g at 136.

II. Physician-Administered Drugs

A. Dual-Channel Drugs

The same result obtains with respect to drugs that are administered by physicians rather than dispensed by pharmacies. One link between the two classes is the subclass of drugs that fall into both – the so-called "dual-channel" drugs that are both dispensed by pharmacies and administered by physicians. Of the 132 drugs identified in the AMCC for the Track 1 defendants, at least 20 are offered through both channels. Sur-Reply of Steven J. Young in Opp'n to Pls.' Mot. for Class Certification at 15 n.23 (hereinafter "Young Sur-Reply").[2] As to these drugs, payors who participate directly or through PBMs in the complex negotiations that characterize reimbursement of pharmacies may draw upon the results of those negotiations when considering what rates to pay physicians for administering the very same drugs. They may also make reasonable inferences from their experience with these dual-channel drugs concerning reimbursement of physicians for administering other drugs, thereby importing into the realm of physician-administered drugs more broadly the range of economic factors affecting negotiated pricing of pharmacy-dispensed drugs.

Members of the Plaintiffs' putative classes are simultaneously reimbursing pharmacies and physicians for the same dual-channel drugs. Thus, the results of the complex operation of economic forces in the pharmacy market are available to these payors as guidelines for negotiations with physicians. Whether payors heed these guidelines and to what extent are matters of individual inquiry that certainly cannot be averaged. The broader significance of

2

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dual-channel drugs – the inferences they permit about drugs that are not sold through both pharmacies and physicians – likewise cannot be swept beneath the average rug.

B. Cross-Subsidization

Reimbursement for physician-administered drugs typically includes payment for drug costs as well as drug administration. Drug ingredient costs often are not separately stated, by reference to AWP or otherwise. When they are separately stated, as in Medicare Part B and various Blue Cross Blue Shield Plans, physicians and insurers alike still evaluate reimbursement based on payment as a whole. *See, e.g.*, a source cited by the Plaintiffs themselves, Dyckman & Associates, *Health Plan Payment for Physician-Administered Drugs*, Medicare Payment Advisory Comm'n (Aug. 2003), attached to Written Tutorial of Meredith Rosenthal as Ex. 14. Private and public payors alike recognize that reimbursement of ingredient costs often is used to subsidize inadequate reimbursement of administration services. Thus, as reported in 2003 by the Dyckman study cited by the Plaintiffs, private payors subsidize what physicians contend (and the payors accept) to be inadequate reimbursements for their services in connection with administering the drug by providing higher reimbursement payments for the costs of the drugs themselves. *Id*. The same is so in the realm of public reimbursement.[3] The extent of cross-subsidization is not uniform; individualized inquiry is unavoidable to ascertain its impact.

In this setting, considering the impact of dual-channel drugs and cross-subsidization, the impact of changes in AWP on reimbursement rates for physician-administered drugs is more diffuse and less predictable than in the context of pharmacy reimbursement, where it is already

[3] For example, new Medicare regulations have increased the fee for administering inhalation therapies such as albuterol by more than 10-fold, from $5 to $57, to compensate for a reduction in reimbursement for the ingredient itself from 95% of AWP to ASP + 6%. *See* Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, 69 Fed. Reg. 66,236-01 (Nov. 15, 2004) (to be codified at 42 CFR pts. 403, 405, 410, 411, 414, 418, 424, 484,and 486).

sufficiently diffuse and unpredictable to preclude class certification. The ripple effects of changes in AWP on reimbursement rates in this market are dampened by more forces in more complex ways than are such changes in the pharmacy market.

III. MAC Pricing and Median AWP Reimbursement

A. MAC Pricing

PBMs and payors often reimburse generics based on Maximum Allowable Cost ("MAC") rather than AWP, with each PBM or payor using its own proprietary formula to develop its own MAC lists. A MAC price for a generic drug might or might not use AWP as a definitive factor; some do and some do not. *See* Rebuttal Decl. of Eric M. Gaier in Support of Defs.' Opp'n to Class Certification ¶ 53.[4]

The question for class certification is whether a change in AWP predictably and uniformly affects members of the putative class by changing MAC prices predictably and uniformly. The answer to that question is demonstrably negative: MAC prices that make no reference to AWP probably would not change in response to a change in AWP; those that do refer to AWP as one among several factors might or might not be affected by a change in AWP, depending on the specific way in which AWP interacted with the other factors; a contract-by-contract and probably transaction-by-transaction analysis would be required to determine whether a change in AWP would have had an impact on reimbursement.

[4] Plaintiffs concede the variable use of AWP in MAC pricing. *See, e.g.*, Plaintiffs' Reply to Schering-Plough Group's Individual Mem. in Opp'n to Class Certification at 7, **CONFIDENTIAL INFORMATION REDACTED**; *Id.* at 5, n.6; *Id.* at 7, citing Schondelmeyer Tr. at 371 and 447-48 (PBM's MAC prices rely *at least in part* on published AWP *or* WAC prices) (emphasis added).

B. Median AWP Reimbursement

Payors who use median AWPs as a basis for reimbursing generic drugs might or might not be affected by changes in a particular AWP, depending on whether the change affects the median.[5] More importantly, payors such as Medicare Part B and the Blue Cross Blue Shield plans surveyed by Dyckman & Associates who use drug reimbursement to cross-subsidize drug administration services might or might not change their total reimbursement – for ingredient and service – as a result of a change in AWP, depending upon the extent of cross-subsidization that had previously been in place and the level that the parties would negotiate in the changed circumstance, which is tied to individual circumstances and cannot be determined on a class-wide basis.

CONCLUSION

Plaintiff's Motion for Class Certification should therefore be DENIED.

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[5] It is a matter of arithmetic that not all changes in AWP will change the median. To illustrate: Assume five manufacturers A-E reporting AWPs for a generic drug, with A=1, B=5, C=25, D=50, E=100. The median AWP is 25. E and D can decrease their AWPs by 50% and 75% respectively without changing the median (A=1, B=5, C=25, D=25, E=25; the median remains 25). A and B can raise their AWPs by 2500% and 500% respectively without changing the median (A=25, B=25, C=25, D=50, E=100; the median remains 25).

CERTIFICATE OF SERVICE

I hereby certify that on February 4, 2005, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456

/s/ Eric P. Christofferson
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